Amendment and post-card receipt are enclosed herein. Accordingly, it is respectfully requested that the objection to claim 10 be withdrawn.

II. CLAIMS 1-7 ARE DEFINITE

Claims 1-7 stand rejected under 35 U.S.C. § 112, second paragraph. This rejection is respectfully traversed for the following reasons. The Examiner alleges that claim 1 is incomplete because "there is no correlation step recited between the light intensities and the protein amount [and] absent such a recitation, it is not clear how the concentration of the protein can be measured." It is respectfully submitted that the Examiner's allegations are directed to claim ***scope*** rather than claim ***definiteness***. The Examiner is directed to MPEP § 2173.04 under the section entitled "Breadth is Not Indefiniteness" which sets forth the applicable standard.

In the instant case, it is respectfully submitted that the scope of claim 1 is definite and embodies any means to measure the light intensities and determine the concentration of protein based on the light intensities (*see* Applicant's specification for various non-limiting examples). It is not necessary for claim 1 to recite an additional step defining specifically "how" the protein concentration is determined to satisfy the requirements of § 112, second paragraph.

It is noted that claim 1 sets forth that the "determining" step is conducted "based on said intensities" so as to define a relationship between steps (a) and (b). Based on this relationship, one of ordinary skill in the art could readily perform the steps of claim 1 using any available means for measuring light intensity and determining protein concentration based on the measured light intensity so as to render the scope of claim 1

definite. That is, one of ordinary skill in the art, having performed step (a) of claim 1, would be able to choose any known means to determine a concentration of protein in the solution based on the results of step (a).

Applicant is not obligated to restrict the scope of the claimed invention to define only a single means of determining the protein concentration based on the results of step (a). Again, the particular manner by which the steps are performed is not a matter of claim definiteness analyzed under § 112, but rather, a matter of claim scope analyzed under § 102/103.

Based on the foregoing, it is submitted that claims 1-7 are definite. Accordingly, it is respectfully requested that the rejection of claims 1-7 under 35 U.S.C. § 112, second paragraph be withdrawn.

III. CLAIM 13 IS DEFINITE

Claim 13 stands rejected under 35 U.S.C. § 112, second paragraph. This rejection is respectfully traversed for the following reasons. Although appreciated, it is submitted that the Examiner's suggested amendment to claim 13 is unduly limiting and without basis in relation to § 112. That is, the Examiner has not indicated why claim 13 is believed to be indefinite, and Applicant submits that claim 13 as it currently reads is definite.

Turning to the Examiner's suggested amendment, the Examiner requests the addition of "a pH controlling agent" to the reagent. However, as discussed on page 8, lines 4-7 of Applicant's specification, the reagent itself can sometimes function as a pH controlling agent so that the addition of a separate pH controlling agent is not necessary.

Accordingly, the scope of claim 13 is definite in that it embodies both the addition of a pH controlling agent and the reagent functioning as the pH controlling agent. Again, it is submitted that claim breadth is not claim indefiniteness as set forth in MPEP § 2173.04.

Based on the foregoing, it is submitted that claim 13 is definite. Accordingly, it is respectfully requested that the rejection of claim 13 under 35 U.S.C. § 112, second paragraph be withdrawn

IV. CLAIMS 1, 5-7, 12, 14, 15 AND 17 ARE PATENTABLE OVER COREY

Claims 1, 5-7, 12, 14, 15 and 17 stand rejected under 35 U.S.C. § 103 as being unpatentable over Corey ('589). This rejection is respectfully traversed for the following reasons. The indication of allowable subject matter in claim 13 is acknowledged and appreciated. In order to expedite prosecution, claim 12 has been amended to include the allowable subject matter of claim 13. Accordingly, it is respectfully submitted that claim 12 and its dependent claims 14-17 are in condition for allowance.

Claim 1 recites in pertinent part, "measuring intensities ... before and after mixing therein" a reagent. The Examiner admits that this step is not expressly disclosed by Corey, but alleges that "it is clear that this step has been performed in order to generate the spectrophotometric standard curve used to calibrate protein amount." As a preliminary matter, it is submitted that the steps involved in generating standard curves are not part of the process for "measuring a concentration of protein" as recited in claim 1. That is, generating standard curves is based on samples whose protein concentrations are already known so as to generate curves which show the relationship between protein concentrations and detected light intensity. The process of generating standard curves is

separate and distinct from a process for measuring protein concentration of a test sample having an unknown protein concentration. Accordingly, it is submitted that the Examiner's reliance on the process related to generating standard curves is not applicable to the process of measuring a concentration of protein recited in claim 1.

Furthermore, the Examiner has effectively taken the position that measuring light intensity both before and after mixing a reagent is inherent in Corey. However, contrary to the Examiner's assertion, it is NOT necessary to measure light intensity both before and after mixing the reagent. Only Applicant discloses such a process and the advantages thereof, whereas Corey is completely silent to measuring light intensities before and after mixing the reagent. In fact, it is typical to determine protein concentration using the conventional manner of measuring light intensity only after the reagent is mixed. As is well known in patent prosecution, "inherency may not be established by probabilities or possibilities" (*see Scaltech Inc. v. Retec/Tetra*, 178 F.3d 1378 (Fed. Cir. 1999)).

In the instant case, Corey does not even suggest the possibility nor probability of measuring light intensities before the reagent is mixed into the solution, let alone suggest doing so. Again, as mentioned above, the conventional testing procedure makes measurements of the light intensity only after mixing the reagent. However, Applicant has discovered a novel process of measuring light intensity both before and after mixing the reagent so as to provide more accurate results without being influenced by the inherent turbidity of a sample (e.g., urine; *see, e.g.* page 23, line 1- page 24, line 8 of Applicant's specification).

The Examiner is directed to MPEP § 2143.03 under the section entitled "All Claim Limitations Must Be Taught or Suggested", which sets forth the applicable standard:

> To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. (citing *In re Royka*, 180 USPQ 580 (CCPA 1974)).

In the instant case, the pending rejection does not "establish *prima facie* obviousness of [the] claimed invention" as recited in claim 1 because the proposed combination fails the "all the claim limitations" standard required under § 103.

Under Federal Circuit guidelines, a dependent claim is nonobvious if the independent claim upon which it depends is allowable because all the limitations of the independent claim are contained in the dependent claims, ***Hartness International Inc. v. Simplimatic Engineering Co.,*** 819F.2d at 1100, 1108 (Fed. Cir. 1987). Accordingly, as claim 1 is patentable for the reasons set forth above, it is respectfully submitted that dependent claims 2-7 which depend on claim 1 are also patentable. In addition, it is submitted that claims 2-7 are patentable based on their own merits by adding novel and non-obvious features to the combination.

Based on the foregoing, it is submitted that claims 1, 5-7, 12, 14, 15 and 17 are patentable over Corey. Accordingly, it is respectfully requested that the rejection of claims 1, 5-7, 12, 14, 15 and 17 under 35 U.S.C. § 103 over Corey be withdrawn.

V. CLAIM 8 IS PATENTABLE OVER KAWAMURA IN VIEW OF COREY

Claim 8 stands rejected under 35 U.S.C. § 103 as being unpatentable over Kawamura et al. ('922) in view of Corey ('589). This rejection is respectfully traversed

for the same reasons discussed above with respect to claim 1. In particular, neither Corey nor Kawamura et al., alone or in combination, disclose or suggest, *inter alia*, "measuring intensities ... before and after mixing therein" a reagent.

The Examiner is directed to MPEP § 2143.03 under the section entitled "All Claim Limitations Must Be Taught or Suggested", which sets forth the applicable standard:

> To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. (citing *In re Royka*, 180 USPQ 580 (CCPA 1974)).

In the instant case, the pending rejection does not "establish *prima facie* obviousness of [the] claimed invention" as recited in claim 8 because the proposed combination fails the "all the claim limitations" standard required under § 103.

Furthermore, it is respectfully submitted that the proposed combination is improper because the Examiner has not provided the requisite ***objective*** evidence ***from the prior art*** that "suggests the desirability" of the proposed combination. The Examiner attempts to modify Kawamura et al. by including the precipitating agent taught by Corey. However, it respectfully submitted that Kawamura et al. and Corey are directed to ***distinct*** opacifying processes and there is no motivation from the prior art that would suggest the desirability of combining the two opacifying processes. Kawamura et al. is directed to a process of opacifying the solution by ***heating*** (*see* Abstract) whereas Corey discloses a process of opacifying the solution by ***using a precipitating agent***. Corey does NOT disclose using a precipitating agent as a secondary opacifier in addition to a primary opacifier. Rather, Corey discloses using the precipitating agent as a primary opacifier, whereas Kawamura et al. discloses heating as the primary opacifying means.

These two distinct opacifying processes (heating by Kawamura et al. and precipitating agent by Corey) are independent of one another and neither Kawamura et al. nor Corey suggest a need or desire for the combination of the two precipitating processes into a single process as set forth in the proposed combination, nor suggest a preference of using the precipitating agent of Corey in place of the heating used in Kawamura et al.. Accordingly, it is respectfully submitted that the Examiner selected bits and pieces of the prior art and relied solely on improper hindsight reasoning using only Applicant's specification as a guide to reconstruct the claimed invention.

As is well known in patent law, a *prima facie* showing of obviousness can only be established if the prior art "suggests the desirability" of the proposed combination using ***objective*** evidence. The Examiner is directed to MPEP § 2143.01 under the subsection entitled "Fact that References Can Be Combined or Modified is Not Sufficient to Establish *Prima Facie* Obviousness", which sets forth the applicable standard:

> The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. (*In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990)).

In the instant case, even assuming *arguendo* that Kawamura et al. can be modified by Corey, it is submitted that the "mere fact that [Kawamura et al. and Corey] can be combined ... does not render the resultant combination obvious" because nowhere does the ***prior art*** "suggest the desirability of the combination" as set forth by the Examiner.

The Examiner is further directed to MPEP § 2143.01 under the subsection entitled "Fact that the Claimed Invention is Within the Capabilities of One of Ordinary Skill in the Art is Not Sufficient by Itself to Establish *Prima Facie* Obviousness", which sets forth the applicable standard:

> A statement that modifications of the prior art to meet the claimed invention would have been [obvious] because the references relied upon teach that all aspects of the claimed invention were ***individually*** known in the art is ***not*** sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. (citing *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993)).

In the instant case, even assuming *arguendo* that Kawamura et al. and Corey "teach that all aspects of the claimed invention [are] individually known in the art", it is submitted that such a conclusion "is not sufficient to establish a *prima facie* case of obviousness" because there is no ***objective*** reason on the record to combine the teachings of the cited prior art in the manner suggested by the Examiner. As mentioned above, neither Kawamura et al. nor Corey suggest using the combination of two opacifying processes as a single process or replacing heating with a precipitating agent.

Under Federal Circuit guidelines, a dependent claim is nonobvious if the independent claim upon which it depends is allowable because all the limitations of the independent claim are contained in the dependent claims, ***Hartness International Inc. v. Simplimatic Engineering Co.,*** 819F.2d at 1100, 1108 (Fed. Cir. 1987). Accordingly, as claim 8 is patentable for the reasons set forth above, it is respectfully submitted that dependent claims 9-11 which depend on claim 8 are also patentable. In addition, it is submitted that claims 9-11 are patentable based on their own merits by adding novel and non-obvious features to the combination.

Based on the foregoing, it is submitted that claims 8-11 are patentable over Kawamura et al. in view of Corey. Accordingly, it is respectfully requested that the rejection of claim 8 under 35 U.S.C. § 103 over Kawamura et al. in view of Corey be withdrawn.

VI. NEW CLAIMS

The indication of allowable subject matter in claims 2-4, 9-11 and 16 is acknowledged and appreciated. New claim 18 includes what is believed to be the allowable subject matter of claim 2, new claim 19 includes what is believed to be the allowable subject matter of claim 3, new claim 20 includes what is believed to be the allowable subject matter of claim 4, new claim 24 includes what is believed to be the allowable subject matter of claim 9, new claim 25 includes what is believed to be the allowable subject matter of claim 10, new claim 26 includes what is believed to be the allowable subject matter of claim 11, and new claim 28 includes what is believed to be the allowable subject matter of claim 16.

New claim 21 includes the subject matter of claim 5 and new claim 27 includes the subject matter of claim 14. Claims 5 and 14 stand rejected under 35 U.S.C. § 103 as being unpatentable over Corey. However, the Examiner does not identify how Corey allegedly discloses the features of claims 5 and 14, and in fact, it is respectfully submitted that Corey does NOT disclose or suggest the features of claims 5 and 14 now incorporated into new claims 21 and 27, respectively.

Claim 21 recites in pertinent part, "wherein the protein concentration in said solution to be detected is determined based on the intensities of said transmitted light ***and*** said scattered light" (emphasis added). The Examiner relies on Corey to reject claim 5, but does not identify how Corey discloses the feature recited therein. Indeed, Corey appears silent as to the type of light being measured (i.e., transmitted or scattered), let alone disclose using ***both*** transmitted light and scattered light. As described on, for example, page 16, lines 4-14 of Applicant's specification, measuring both types of light

intensities can eliminate conventionally needed steps such as diluting solutions in the high concentration range, thereby increasing accuracy and efficiency, etc.. Claims 22 and 23 add further novel and non-obvious features to claim 21.

Claim 27 recites in pertinent part, "wherein said reagent contains at least one selected from the group consisting of tannin, tannic acid and m-galloyl gallic acid, [and] wherein said reagent contains one acid selected from the group consisting of potassium hydrogen phthalate, acetic acid, citric acid and ascorbic acid as a pH controlling agent." The Examiner relies on Corey to reject claim 14, but does not identify how Corey discloses the feature recited therein. Indeed, Corey appears silent as to a reagent containing an "acid selected from the group consisting of potassium hydrogen phthalate, acetic acid, citric acid and ascorbic acid as a pH controlling agent", let alone disclose a reagent containing the aforementioned acid in combination with at least one selected from "tannin, tannic acid and m-galloyl gallic acid."

The Examiner is directed to MPEP § 2143.03 under the section entitled "All Claim Limitations Must Be Taught or Suggested", which sets forth the applicable standard:

> To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. (citing *In re Royka*, 180 USPQ 580 (CCPA 1974)).

In the instant case, the pending rejection does not "establish *prima facie* obviousness of [the] claimed invention" as recited in claims 21 and 27 because the proposed combination fails the "all the claim limitations" standard required under § 103.

For all the foregoing reasons, it is respectfully submitted that new claims 18-28 are patentable over the cited prior art.

VII. CONCLUSION

Having fully and completely responded to the Office Action, Applicants submit that all of the claims are now in condition for allowance, an indication of which is respectfully solicited. If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicants' attorney at the telephone number shown below.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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APPENDIX

2. (Amended) The method for measuring a concentration of protein in accordance with claim 1, further comprising a step of:

(a') regulating a pH of a solution to be detected to 1.5 to 5.8 after mixing therein said reagent [in said step (a)].

3. (Amended) The method for measuring a concentration of protein in accordance with claim 2, wherein the pH of the solution to be detected is regulated by adding a pH controlling agent selected from the group consisting of potassium hydrogen phthalate, acetic acid, citric acid and ascorbic acid in said solution to be detected [in said step (a')].

4. (Amended) The method for measuring a concentration of protein in accordance with claim 1, wherein a concentration of a reagent in a solution to be detected after mixing therein said reagent is in the range of 5×10^{-3} to 5 g/dl [in said step (a')].

7. (Amended) The method for measuring a concentration of protein in accordance with claim 5, further comprising a step of:

(c) detecting the presence or absence of an erroneous measurement due to a suspending particle such as a bubble in said solution to be detected by comparing the intensity of said transmitted light with that of said scattered light.

9. (Amended) The method for measuring a concentration of a solution in accordance with claim 8, further comprising a step of:

(i') regulating a pH of said solution to be detected to 1.5 to 5.8 after mixing therein said reagent [in said step (i)].

11. (Amended) The method for measuring a concentration of a solution in accordance with claim [9] 8, wherein a concentration of a reagent in a solution to be detected after mixing therein said reagent is in the range of 5×10^{-3} to 5 g/dl [in said step (i')].

12. (Amended) A reagent for measuring a concentration of protein to be used in a method for measuring a concentration of protein in which a reagent is mixed in a solution to be detected and a concentration of protein is determined from the resulting turbidity,

wherein said reagent contains at least one selected from the group consisting of tannin, tannic acid and m-galloyl gallic acid,

wherein the pH thereof is regulated to the range of 1.5 to 5.8.

17. (Amended) The reagent for measuring a concentration of protein in accordance with claim [13] 14, wherein the concentration of said pH controlling agent is at the highest possible level as long as said p[h]H controlling agent does not deposit in a temperature range operable for said reagent.